

Applicant : Rourke, et al.  
Appl. No. : 09/664,970  
Examiner : Ho, Uyen T.  
Docket No. : 702563.46

### **Remarks**

This is responsive to the Office Action mailed on May 4, 2004. Applicant greatly appreciates the allowance of claims 10-20, 37 and 39. Claims 1, 9-20, 37 and 39 are currently pending.

In the Office Action, the Examiner rejected claims 1 and 9 under 35 U.S.C. 103(a) based on the combination of Cox '758 in view of Martinez et al. '909. Applicant respectfully requests reconsideration of this rejection.

Claims 1 and 9 recite that the flexible leaflets are deflectable from a closed position to an open position "without exposure to a softening liquid." This distinguishes these claims from the combination of the Cox and Martinez et al. patents. Specifically, the Martinez et al. patent requires a softening liquid, such as a warm saline solution, to facilitate flexing of the section in the distal end portion of the sheath between the weakened areas or slits. (See Col. 4, ll. 44-55). Accordingly, because a limitation of the present claims is not taught or suggested by either of the references cited by the Examiner, there can be no prima facie case of obviousness of the present claims.

In the Office Action, the Examiner stated that the functional statement "without exposure to a softening liquid" imposed no structural limitation on the claims distinguishable over the device of Cox in view of Martinez. Applicant respectfully disagrees. To begin, there is nothing wrong with using functional language in a claim to define the subject matter of an invention. See *In re Swinehart*, 439 F.2d 210, 169 USPQ 226 (CCPA 1971). In addition, the claim language "the leaflets being deflectable, without exposure to a softening liquid" structurally distinguishes the claims from Cox in view of

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Martinez. This is because the claim language "the leaflets being deflectable, without exposure to a softening liquid" requires that the leaflets be of a structure that is deflectable without exposure to a softening liquid, and is therefore structurally distinguishable from a structure that requires a softening liquid to facilitate flexing. Because the Martinez et al. patent requires a softening liquid to facilitate flexing of the section in the distal end portion of the sheath between the weakened areas or slits, the claims are structurally distinguishable from the combination of the Cox and Martinez et al. patents.

Claims 1 and 9 are also patentable because the motivation to combine the Cox patent and Martinez et al. patent is improper. To establish a prima facie case of obviousness, there must be some suggestion or motivation, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art to combine the references. See MPEP § 706.02(j). Here, there is no suggestion or motivation in the Cox and Martinez et al. patents to combine them in the manner chosen by the Examiner. The Cox and Martinez et al. patents neither teach nor suggest the problem of leaflets flaring out and damaging the wall of a blood vessel during advancing of Cox's delivery system into a vessel, or that it is a problem that should be solved by employing weakened regions between the plurality of slits/leaflets of Cox's sheath. Instead, it appears that the Examiner based the motivation to combine the Cox and Martinez et al. patents on the applicant's disclosure, which the Examiner is not allowed to do. See *In re Vaeck*, 947 F.2d 488, 20 USPQ2d 1438 (Fed. Cir. 1991). More particularly, it appears that the Examiner based the motivation to combine the Cox and Martinez et al. patents on page 33, lines 9-17 of the applicant's disclosure. Because the Examiner has not shown a

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motivation to combine that is either in the references themselves or in the knowledge generally available to one of ordinary skill in the art, the Examiner has failed to establish a prima facie case of obviousness. For this additional reason, the rejections stated in the Office Action should be withdrawn, and all claims allowed.

### **CONCLUSION**

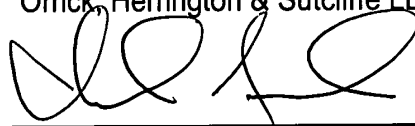
In view of the foregoing, it is submitted that the claims presented in this application define patentable subject matter to which Applicant is entitled. Accordingly, consideration and allowance of the application is requested.

Respectfully submitted,

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